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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,229	04/23/2001	Venkata-Rangarao Kanikanti	LEA 33 253	8002

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,229

Applicant(s)

KANIKANTI ET AL.

Examiner

Humera N Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made of the Declaration filed 04/23/01, the Preliminary Amendment and the IDS filed 03/16/01 and the IDS filed 12/03/01.

Claims 1-8 and 12 are pending. Claims 1-8 and 12 are rejected. Claims 9-11 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are directed to a process for the production of an orally administerable multiple-unit sustained-release dosage formulation. The claims do not recite the steps for the process of production in a clearly stated fashion. Appropriate correction is required, as needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jenkins *et al.* (EP 0 205 282 B1).

Jenkins *et al.* disclose a process for the preparation of a sustained release, oral pharmaceutical composition, comprising a hydrophilic polymer HPC (hydroxypropyl cellulose), (average molecular weight of greater than 200,000 and greater than 500,000), and a pharmaceutically active compound, wherein the percentages of HPC appear to fall within the claimed amounts and the active-compound polymer mixture is formed into coated granules having a particle size of less than 1000 micrometers for use in oral administration dosage forms (see reference pages 2-4 and examples).

Jenkins *et al.* do not explicitly disclose a molar degree of substitution of at least three. However, Jenkins *et al.* uses the same hydrophilic polymer HPC in the same amounts as the instantly claimed invention, and therefore the molar degree of substitution would also be expected to be similar as the instant claims.

Claims 1-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jenkins *et al.* (US Pat. No. 4,940,587).

Jenkins *et al.* disclose a process for the preparation of a sustained release, oral pharmaceutical composition, comprising a hydrophilic polymer HPC (hydroxypropyl cellulose), (average molecular weight of greater than 200,000 and greater than 500,000), and a pharmaceutically active compound, wherein the percentages of HPC appear to fall within the claimed amounts and the active-compound polymer mixture is

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formed into coated granules having a particle size of less than 1000 micrometers for use in oral administration dosage forms (see reference columns 2-3 and examples).

Jenkins et al. do not explicitly disclose a molar degree of substitution of at least three. However, Jenkins et al. uses the same hydrophilic polymer HPC in the same amounts as the instantly claimed invention, and therefore the molar degree of substitution would also be expected to be similar as the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins *et al.* (EP 0 205 282 B1) or Jenkins *et al.* (US Pat. No. 4,940,587).

Jenkins et al. (EP 0 205 282 B1 and US Pat. No. 4,940,587) teach a process for the preparation of a sustained release, oral pharmaceutical composition, comprising a hydrophilic polymer HPC (hydroxypropyl cellulose), (average molecular weight of greater than 200,000 and greater than 500,000), and a pharmaceutically active compound, wherein the percentages of HPC appear to fall within the claimed amounts and the active-compound polymer mixture is formed into coated granules having a particle size of less than 1000 micrometers for use in oral administration dosage forms

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(see EP reference pages 2-4 and examples and US reference columns 2-3 and examples).

Jenkins et al. do not explicitly disclose a molar degree of substitution of at least three. This was discussed above. It is unclear whether Jenkins et al. teaches the different degrees of molar substitution being well above three. Assuming that these are different and in the absence of showing otherwise, it is deemed obvious to one of ordinary skill in the pharmaceutical art to obtain a suitable degree of molar substitution through routine or manipulative experimentation to obtain the best possible results. The expected result would be a process for the preparation of a sustained release oral formulation having the same intended purpose and outcome using an effective degree of molar substitution as similarly desired by the Applicant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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